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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/497,943	02/04/2000	Mark Aaron Behlke		8098

52229            7590            04/20/2005  
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EXAMINER
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SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
	1634

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/497,943	BEHLKE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 January 2005.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 29-33,35,37-41,43-48,55,56 and 58-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 29-33,35,37-41,43-48,55,56 and 58-64 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Specification***

1. The use of the trademark NYLON, SEPHADEX, AMBION, and NEW ENGLAND BIOLABS have been noted in this application. They should be capitalized wherever they appears and be accompanied by the generic terminology.
2. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

### **New Matter**

4. Claims 55 and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
5. On 18 January 2002, an amendment was filed wherein claims 55 and 56 were added.

55. (New) The method of claim 29, wherein the Probe has a specific activity of at least  $7 \times 10^7$  CPM per picomole, and wherein the Probe comprises the Target Binding Domain, the Template Hybridization Domain and the Signal Domain.

56. (New) The method of claim 29, wherein the Probe has a specific activity of at least  $9 \times 10^7$  CPM per picomole, and wherein the Probe comprises the Target Binding Domain, the Template Hybridization Domain and the Signal Domain.

While the specification teaches at page 36, lines 30-32, that a probe was generated that “had a specific activity of  $7 \times 10^7$  CPM per picomole,” the specification has not been found to teach an open-ended range of specific activity. Accordingly, the open-ended range of specific activity constitutes new matter.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 29-33, 35, 37-41, 43-48, 55, 56, and 58-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 29-33, 35, 37-41, 43-48, 55, 56, and 58-64 are all drawn to a method of labeling an oligonucleotide. While the method is defined as comprising various steps, a “first oligonucleotide” is now defined in terms of consisting essentially of certain domains. While the use of the phrase “consisting essentially of” is recognized as allowing for the inclusion of additional ingredients in a composition so long as it does not alter the basic novel features of said

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composition, the term has not been defined in terms of what constitutes the basic and novel features of the oligonucleotide. Claims 30-33, 35, 37-41, 43-48, 55, 56, and 58-63, which depend from said claim 29, fail to overcome this issue and are similarly rejected.

9. Similar issues exist with respect to usage of the phrase in claim 32, 40, and 64.

***Conclusion***

10. Rejections and/or objections that appeared in the prior Office action and not repeated hereinabove have been withdrawn.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

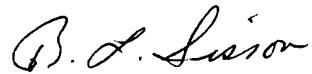
The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson  
Primary Examiner  
Art Unit 1634

BLS  
18 April 2005